MAR 1 2 2013

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

The Assigned 510(k) Number is: K121864

Date: March 8, 2013

Submitted by:	PerkinElmer Health Sciences 17 P&N Drive Greenville, SC 29611
Contact Person:	Kay A. Taylor Tel: 317-418-1735 Fax: 317-536-3064
Trade Name:	PerkinElmer 226 Sample Collection Device
Common Name: **Regulation:**	Blood Specimen Collection Device 21 CFR 862.1675
Classification Name:	tubes, vials, systems, serum separators, blood collection
Product Code:	JKA
Predicate Device(s):	Ahlstrom 226 Specimen Collection Paper - K062932 Whatman 903 Specimen Collection Paper - pre-amendment device
Device Description:	PerkinElmer 226 Sample Collection Device is designed to provide a uniform surface for the collection of blood spots. A drop of blood is applied to the filter paper and allowed to soak through the paper. The sample is then air dried and sent to a laboratory for further analysis. The PerkinElmer 226 Sample Collection contains Ahlstrom 226 filter paper that is made from 100% pure cotton linters with no wet-strength additives added and conforms to the Recognized Standard CLSI LA4-A4. The Ahlstrom 226 filter paper has four performance characteristics that can be assessed with lysed or intact red blood cells; blood absorption time, blood spot diameter, serum absorption volume and homogeneity. Physical properties of the Ahlstrom 226 filter paper monitored during manufacturing

are basis weight, pH and ash content. Basis weight should be 110 lb ± 5% per ream (179 g/m^2 ± 5%). A ream is defined as 500 sheets 24" x 36" (ASTM D646-96). The pH should be 5.7 to 7.5 (Test method ISO 6599:1981). Ash percent limit is a maximum of 0.1% (Test method A of ASTM D586-97a). Ahlstrom (manufacturer of paper) name and lot number appears on the PerkinElmer 226 Sample Collection Device along with a PerkinElmer specific lot identifier.

When used in newborn screening, the PerkinElmer 226 Sample Collection Device demographic form should contain (at a minimum) the following information.

- Infant's name [last (and first available)]
- Mother's first and last name
- Gender
- Birth date (optional: include time of birth)
- Date of specimen collection
- Infant's age (indicate if less than 24 hours; optional: include address and phone number)
- Patient ID number (e.g., medical record number; optional: include address and phone number)
- Birth weight
- Submitter's ID and address (optional: include birth facility)
- Physician's name (healthcare provider) and telephone number
- Name of newborn screening program and address
- Unique non-repeating serial number
- Expiration date of specimen collection device
- Appropriate number of preprinted circles
- Manufacturer and lot number of the filter paper
- Manufacturer or printer of the Sample Collection Device

The Ahlstrom 226 filter paper component is supplied to PerkinElmer Health Sciences where production of the final device which involves printing on the filter paper, affixing the filter paper to the carrier device to provide rigidity and, if required, affixing a tear-apart form for the collection of demographic information is performed. Depending on the end users requirements the final device may be only the printed filter paper with carrier device or printed filter paper with carrier device and demographic form which may be comprised of multiple sheets.

Intended Use: The PerkinElmer 226 Sample Collection Devices are intended to be used as a medium to collect and transport whole blood specimen spots to a laboratory, in newborn screening. The device includes a tear-apart form for the collection of demographic information.

Substantial Equivalence: The PerkinElmer 226 Sample Collection Device is substantially equivalent to Ahlstrom 226 Specimen Collection Paper (K062932) device. The follow table provides a summary of device comparison.

Device Similarities and Differences

Characteristic	**PerkinElmer 226 (New Device)**	**Ahlstrom 226 (Predicate Device)**
Intended Use	The PerkinElmer 226 Sample Collection Devices are intended to be used as a medium to collect and transport whole blood specimen spots to a laboratory, in newborn screening. The device includes a tear-apart form for the collection of demographic information.	The Ahlstrom 226 specimen collection paper is intended to be used as a medium to collect and transport blood specimen spots to a laboratory. The collection paper is in the format of a printed card that may be incorporated along with a tear-apart form for the collection of demographic information
Description	Various sizes of Ahlstrom 226 filter paper, printed and affixed to a carrier such as cardboard or plastic; and may be incorporated along with a tear-apart form	Same
Matrix	Whole blood	Same
Storage conditions for unused cards	Store in a cool dry space away from direct sunlight.	Same
Specimen drying time	3 – 4 hours	Same
Standard referenced	CLSI LA4 – A4: Blood Collection on Filter Paper for Newborn Screening Programs	Same

Performance Characteristics:
The FDA recognized consensus standard for the device is the CLSI LA4-A4: Blood Collection on Filter Paper for Newborn Screening Program; Approved Standard. The standard describes four physical properties of the filter paper and acceptance criteria for each. Additionally the CLSI LA4-A4 requires the printing ink and printing process must

not interfere with the analytic test procedure. The PerkinElmer 226 Sample Collection device meets the requirements specified in the CLSI standard.

Physical Properties:

1. **Absorption capacity** as measured by serum retention volume of a 1.8 inch paper punch taken from a dried blood spot. A range of 1.37 – 1.71 µL is considered acceptable.

   Ahlstrom paper lot 1 (mean) 1.477 µL

   Ahlstrom paper lot 2 (mean) 1.443 µL

2. **Homogeneity** of the filter paper lot (spot-to-spot and sheet-to-sheet variability). To perform this test, blood samples tagged with ^{125}I labelled T4 are applied to the filter paper. Samples (punches) of the filter paper are removed from pre-defined areas within the same lot and between lots. By measuring the amount of ^{125}I labelled T4, the homogeneity of the lot is calculated using a hierarchical, nested analysis of variance technique. An F-test is used to test equivalence of the mean values of the lots of paper. A p value of greater than 0.05 is considered acceptable.

   Ahlstrom paper lot 1 p=0.937

   Ahlstrom paper lot 2 p=0.607

3. **Diameter** of the circle for the dried blood aliquot. A range of 15-17 mm left to right and top to bottom is considered acceptable.

   Ahlstrom paper lot 1 (mean) 15.98 mm

   Ahlstrom paper lot 2 (mean) 16.75 mm

4. **Absorption time** for a 100 µL blood aliquot. A range of 5 – 30 seconds is considered acceptable.

   Ahlstrom paper lot 1 (mean) 7.88 seconds

   Ahlstrom paper lot 2 (mean) 12.74 seconds

5. **Printing ink and printing process:** No clinically significant interference was observed with the analytic test procedure of four representative newborn screening assays incorporating immunometric, competitive and enzymatic methodologies.

Assay Performance:

The population data (N=2000/device type) provided by a U.S. newborn screening laboratory during the process of transitioning from the Whatman 903 Specimen Collection Paper to the PerkinElmer 226 Sample Collection Device was analyzed. The analysis showed a non-significant clinical difference in population median values of 2-

10% for all 12 analytes tested. The products tested included NeoGram Amino Acids and Acylcarnitines Tandem Mass Spectrometry test system, AutoDELFIA 17OHP, IRT and T4 kits, Neonatal GALT kit, and Neonatal Biotinidase kit. Hemoglobinopathy data acquired with the Bio-Rad VARIANTnbs Newborn Screening System as showed similar frequency results within the same population.

Based on test results for the GSP Neonatal hTSH and 17OHP kits, the AutoDELFIA Neonatal T4 kit and the Neonatal Total Galactose kit with spiked samples; no interference from the printing ink or printing process was observed.

Conclusion:

The information provided in this premarket notification demonstrates that the PerkinElmer Sample Collection Device is substantially equivalent to the predicate devices; and satisfies the requirements of CLSI LA4-A4.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

PerkinElmer, Inc.
C/o Kay Taylor
VP, Global Regulatory, Quality, and Clinical Affairs
17 P&N Drive
Greenville, SC 29611

FEB 06 2015

Re: K121864
Trade/Device Name: PerkinElmer 226 Sample Collection Device
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood specimen collection device
Regulatory Class: Class II
Product Code: PJC
Dated: February 13, 2013
Received: February 19, 2013

Dear Ms. Taylor:

This letter corrects our substantially equivalent letter of March 12, 2013.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Parts 801 and 809; medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for: Courtney H. Lias, Ph.D.
DIRECTOR
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): **K121864**

Device Name: **PerkinElmer 226 Sample Collection Device**

Indications for Use:

The PerkinElmer 226 Sample Collection Devices are intended to be used as a medium to collect and transport whole blood specimen spots to a laboratory, in newborn screening. The device includes a tear-apart form for the collection of demographic information.

Prescription Use XXXXX (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Yung W. Chan -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k121864

Page 1 of 1